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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/653,717	09/01/2000	Pierre Cesaro	EGYP 3.0-008	5779

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EXAMINER

COOK, REBECCA

ART UNIT PAPER NUMBER

1614

DATE MAILED: 01/25/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/653,717

Applicant(s)

Cesaro et al

Examiner

Rebecca Cook

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-38 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☒ All b) ☐ Some* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 10, 11
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

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Claims 10-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 10-38 the nature of the second component is not clear. How can there be two second components?

It is not clear if the "dopaminergic agonists" in claims 10, 15 and 28 are the same or different than the nicotine or nicotine derivative recited in these claims. Janson et al discloses that nicotine is a dopaminergic agonist.

It is not clear that claim 12 that the dopaminergic agonist is required. Amending it to recite that the second component is selected from bromocriptine or biperiden will overcome this rejection.

There is no antecedent basis in claim 12 for the "second component" of claim 13.

No subject or effective amount are recited in claim 15.

Claims 17 and 29 and 38 do not further limit the claims from which they depend, since on page 3 the term "long-term" is defined as a period of more than three months. It is not clear if the intent is that 3 months and 1 day or 4 months.

In claim 15 the word "improving" is relative. Claim 18 does not further limit the claim 17, since it is inherent that D1 and D2 dopaminergic receptors are associated with neurodegenerative disease. Furthermore, it is not clear if the subject must have more than one disease. Amending claim 15 to recite "A method for improving the functionality of D1 and D2

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dopaminergic receptors in a subject having a neurodegenerative disease comprising...." and canceling claim 18 will overcome these rejections.

No effective amount is recited in claim 28.

In claim 32 the recitation "and/or" is confusing. In re Anderegg 51 USPQ 66.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 10-3~~8~~ are rejected under 35 U.S.C. 103(a) as being unpatentable over ^{Domino}~~Janson~~ et al or applicants' admissions.

Domino et al (abstract, among others) and applicants (pages 2-3) disclose that both nicotine and its derivatives and L-Dopa and dopaminergic agonists, alone and in combination, are useful to treat neurodegenerative disease. The instant claims differ over Domino et al and applicants' admissions in reciting specific combinations, forms and amounts of compositions, duration of treatment and routes of administration. However, in the absence of a showing of unobvious results in Declaration form commensurate in scope with the claims, no unobvious is seen in combining two compounds, each of which is known to be useful to treat the same condition and some of which are taught to be useful together, to form a composition or use in a method to treat the condition for which their use is taught in the art. Furthermore, once said

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method and composition are known specific combinations, forms and amounts of compositions, duration of treatment and routes of administration are within the skill of the artisan.

The Examples have been considered but are not persuasive. Example 1 and Table I does not show synergistic results, decrease in the dose of L-Dopa or control of clinical symptoms. Table II does not discuss control of clinical symptoms. In Tables III and IV it is not clear that the patient continues to receive the claimed second component. They do not show a decrease in the dose of L-Dopa.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Cook whose telephone number is (703) 308-4724. The examiner can normally be reached on Monday through Thursday from 6:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

January 15, 2002